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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,850	10/17/2003	David W. Burke	7404-558	9581

7590 07/17/2007  
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EXAMINER
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NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

MAIL DATE	DELIVERY MODE
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07/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/687,850	<b>Applicant(s)</b> BURKE ET AL.	
	<b>Examiner</b> ALEX NOGUEROLA	<b>Art Unit</b> 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment of May 07, 2007 does not render the application allowable.

### ***Status of Rejections pending since the Office action of November 06, 2006***

2. All previous rejections are withdrawn. Some of the prior art rejections based on Neel and Neel and Feldman have been rewritten in light of Applicant's amendment.

***Claim Rejections - 35 USC § 103***

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1-5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Beaty et al. (US 6,645,368 B1) ("Beaty").

Addressing claim 1, Neel discloses a method of performing a measurement on a biological fluid in a test strip (abstract) comprising

providing a biological fluid test strip (10) including

a capillary fill chamber (66) extending a length along the test strip from an intake opening (68) to a terminus (70)(Figures 1-3),

a first pair of electrodes (22,24) in operative communication with the chamber (Figure 2),

and

a second pair of electrodes (28,30) in operative communication with the chamber (Figure 2);

dosing the test strip with a biological fluid effective to cause the biological fluid to flow from the intake opening toward the terminus (col. 14:43-51);

applying a first test signal to one of the first pair of electrodes  
(col. 14:48-55);

measuring a first response to the first test signal at the other of the first  
pair of electrodes (col. 14:48-55);

maintaining the first pair of electrodes in an inoperative state after the  
measuring the first response (col. 14:55-57);

applying a second test signal to one of the second pair of electrodes  
(col. 14:67 – col. 15:03);

measuring a second response to the second test signal at the other of the  
second pair of electrodes (col. 14:67 – col. 15:03); and

performing a measurement upon the biological fluid after the measuring  
the second response (col. 15:26-28).

The second test signal applied by Neel appears to be just a DC test signal  
(col. 14:67 – col. 15:03).

Beaty discloses applying an AC test signal to test electrodes to determine  
sample volume sufficiency in an electrochemical test strip for determining the  
concentration of a medically significant component of a biological fluid. See the  
abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the  
invention to use an AC test signal as taught by Beaty in the invention of Neel as the  
second test signal because as taught by Beaty both sample identity and sample  
volume can then be determined with little affect from hematocrit, glucose (or other

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analyte) concentration, temperature, bilirubin concentration, uric acid concentration, and oxygen concentration. See 06:20-42.

Addressing claim 2, Neel et al discloses the measuring of the first response to the first test signal is indicative of contact between the first pair of electrodes and the biological fluid (Column 14, lines 48-51).

Addressing claim 3, Neel et al discloses measuring the first response to the first test signal to indicate contact of the first pair of electrodes and the fluid (Column 14, line 63 through Column 15, line 11).

Addressing claim 4, Neel et al discloses measuring the second response to the second test signal to indicate contact of the second pair of electrodes and the fluid (Column 14, lines 48-55).

Addressing claim 5, Neel et al discloses performing a measurement on the biological fluid by applying a test signal to one of the first pair of electrodes (Column 15, lines 47-58).

Addressing claim 16, for the additional limitation of this claim note that Beaty teaches that the second test signal may be a pure AC signal or may have a DC offset. See col. 06:20-57 and col. 11:32-36.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Beaty et al. US 6,645,368 B1 ("Beaty") as applied to claims 1-5 and 16 above, and further in view of Feldman et al. US 6,592,745 B1 ("Feldman").

Neel does not mention providing a third pair of electrodes in operative communication with the chamber wherein the performing a measurement upon the



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biological fluid includes applying a measurement test signal to one of the third pair of electrodes.

Feldman discloses an electrochemical biosensor for performing a measurement on a biological fluid. The biosensor comprises multiple working electrodes (42, 44, 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (col. 49:7-12). It would have been obvious to provide at least one additional pair of electrodes, to form a third electrode pair, as taught by Feldman in the invention of Neel because as taught by Feldman, "... multiple electrode sensors may be used to test a variety of analytes using a single sample ..." and "[m]ultiple electrode sensors may also be used to improve the precision of the resulting readings ...". See col. 48:16-59.

### ***Claim Rejections – 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant has amended independent claim 7 to require a "third pair of electrodes in operative communication with the chamber" and a third step of "measuring an analyte concentration of the biological fluid using the third electrodes." However, no support has been cited nor found for the combination of steps now present in claim 7 of

"first determining when the biological fluid contacts the first electrodes;

second determining when the biological fluid contacts the second electrodes;

determining a fill time value based upon the first determining and the second determining;

comparing the fill time value to a predetermined value; and

third measuring an analyte concentration of the biological fluid using the third electrodes."

Claims 8-11 depend from claim 7 and so also have the same new matter problem.

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9. Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

New independent claim 12 requires the steps of

"applying a first test signal to one of the first pair of electrodes;

measuring a first response to the first test signal at the other of the first pair of electrodes;

maintaining the first pair of electrodes in an inoperative state after the measuring the first response;

applying a second test signal to one of the second pair of electrodes;

measuring a second response to the second test signal at the other of the second pair of electrodes;

applying a measurement test signal to one of the third pair of electrodes after the measuring the second response;

measuring a third response to the third test signal at the other of the third pair of electrodes; and

determining a concentration of an analyte in the biological fluid using the third response."

However, no support has been cited nor found for this combination of steps.

Claims 13-15 depend from claim 12 and so also have the same new matter problem.

***Final Rejection***

10. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguera  
Primary Examiner  
AU 1753  
July 11, 2007